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**CENTRAL FAX CENTER****JUN 05 2008****FAX TRANSMISSION****DATE:** June 5, 2008**PTO IDENTIFIER:** Application Number 10/667,848-Conf. #1385  
Patent Number**Inventor:** Edward F. Ikeguchi et al.**MESSAGE TO:** US Patent and Trademark Office**FAX NUMBER:** (571) 273-8300**FROM:** FULBRIGHT & JAWORSKI L.L.P.

C. Andrew Im

**PHONE:** (212) 318-3359**Attorney Dkt. #:** NY-MSI 203-US (10406788)**PAGES (Including Cover Sheet):** 4**CONTENTS:** Response to Interview Summary (2 pages)  
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**FULBRIGHT & JAWORSKI L.L.P.**

666 Fifth Avenue, New York, New York 10103

**Telephone:** (212) 318-3000 **Facsimile:** (212) 318-3400

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Dated: June 5, 2008

Signature:

  
(Fani Malikouzakis)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Edward F. Ikeguchi et al.

Application No.: 10/667,848

Confirmation No.: 1385

Filed: September 22, 2003

Art Unit: 4143

For: SYSTEM AND METHOD FOR CONTINUOUS  
DATA ANALYSIS OF AN ONGOING  
CLINICAL TRIAL

Examiner: R. J. RAJ

**RESPONSE TO INTERVIEW SUMMARY**

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

In response to the Interview Summary mailed May 1, 2008, Applicant submits the following summary of the personal interview that took place on April 29, 2008 between the applicant, the undersigned representative and the Examiner and his supervisor. Applicant wishes to thank the Examiner and his supervisor for many courtesies extended to the applicant and the undersigned representative during the telephone interview of April 29, 2008.

Among the issues discussed during that interview were the novel features of the present invention over the prior clinical trial analysis system and the irrelevancy of the cited prior art references. That is, none of the cited references are even remotely related to the analysis of clinical trial data, let alone analysis of clinical trial data while the clinical trial is ongoing. The

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primary reference (U.S. Published Patent Application No. 2002/0099302 to Bardy (hereinafter "Bardy")) cited by the Examiner relates to an automated patient care system and method for providing diagnosis and monitoring congestive heart failure. The secondary reference (U.S. Patent No. 5,978,751 to Pence et al. (hereinafter "Pence")) cited by the Examiner relates to a manufacturing test method and apparatus for testing devices, specifically magnetic disk drives. One of ordinary skill in the art would not be remotely motivated to combine these unrelated references, and even if he did, it would not result in the present invention. Only the present invention teaches or suggests continuously analyzing the trial data of an ongoing clinical trial for a statistically significant event (i.e., when the result of the statistical analysis exceeds a predetermined threshold). Applicant explained to the Examiner that all of the prior art systems and methods describe analyzing clinical trial data only after the clinical trials have ended because they do not want to risk compromising the integrity of the trial data, and thereby jeopardize the veracity of the clinical trial. Nevertheless, to expedite the prosecution of this application, Applicant agreed to amend the independent claims to include limitations that the ongoing clinical trial is a blinded clinical trial comprising a multi-arm study.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-MSI 203-US (10406788) from which the undersigned is authorized to draw.

Dated: June 5, 2008

Respectfully submitted,

By 

C. Andrew Im

Registration No.: 40,657

FULBRIGHT &amp; JAWORSKI L.L.P.

666 Fifth Avenue

New York, New York 10103

(212) 318-3000

(212) 318-3400 (Fax)

Attorney for Applicant

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Application No. (if known): 10/687,848

Attorney Docket No.: NY-MSI 203-US

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on June 5, 2008  
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Response to Interview Summary (2 pages)